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10/684,836	10/15/2003	Tooru Morita	50395-234	9853

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EXAMINER	
MENON, KRISHNAN S	

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1723	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

PTOL-90A (Rev. 04/07)

Office Action Summary	Application No. 10/684,836	Applicant(s) MORITA ET AL.
	Examiner Krishnan S. Menon	Art Unit 1723

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6,8 and 10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6,8 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 6, 8 and 10 are pending as amended on 6/6/07.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1,8 and 10 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms (L) and (Y) have no antecedent basis.

Claims 1,8 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01.

Applicant's arguments and supporting evidence was considered, and accordingly, the 'maximum fibril length' is being considered the same as the 'maximum length of pores'. It is also clarified that the term 'maximum length of pores' is interpreted as the cross-sectional length of pore at the membrane surface, in the light of specification page 15 lines 21-23, and applicant's arguments of 6/5/06

The omitted structural cooperative relationships are: the relationship between the variables X, Y and mean maximum length of pore, and the plot of the ten points. The claim language does not relate it to any specific structural characteristic of the membrane. This limitation is indefinite because it really does not define any metes and bounds for the claimed structure. Claim language includes any particle size that would be trapped to 90% or greater.

For example, in applicant's comparative example 1, with L=15 μm and X = 0.2 μm, the RFL or Y value of 75 would not fit within the claimed region. However, if one were filtering the particles of Example 2, i.e., 2 μm, with the same membrane, then the RFL of 7.5 would fall within the region as shown in the art rejection below. Therefore, the membrane of the same structure is found meeting the claim in one instance and not meeting the claim in another instance, which leads to indefiniteness.

In the arguments submitted on 6/6/07, applicant stated that:

> As noted above, "X" is merely a title/name which identifies a particular grade of a filter which has been standardized in the industry. One of ordinary skill in the art will recognize that X=2 μm and X=.2 μm, by definition, refer to different filters. In this regard, the Examiner's example on page 3, lines 3-8 of the outstanding Office Action purportedly evidencing why claim 1 is indefinite, is based on the false assumption that X=2 μm and X=.2 μm can refer to the same membrane.

In these arguments' applicant is now attempting to define (X) as the micron-rating of the membrane. However, Claim 1 defines (X) as diameter of particles captured with a trapping ratio of 90% or more. So, if the membrane captures 0.2 μm particles to >90%, it would definitely capture 2 μm particles to greater than 90%. The office must consider what is presented in the claims and what is disclosed by the applicant; not what the industry standard says.

In addition, Applicant's example 2 at paragraph [0104] of the Pre-Grant Publication has (L) as 40 μm, and particle size (X) as 2 μm. For this, (Y) will be 20, and this support will not fall in the region (M) of figure 1. However, in paragraph [0105], with the porous expanded PTFE sheet applied as the filtration layer, the (X) value used is 5 μm. (L) is 15 μm, and the corresponding (Y) value of 3 would fall within the region (M). There is no rationale for using the 5 μm particle for this part of the experiment. Since the support layer has a catching performance of 90% for 2 μm particles, after addition of the rejection layer, the membrane should still capture the 2 μm particles to greater than 90%. Then why would the experiment be conducted with 5 μm particles?

For examination, the values of X and Y are considered as optimizable variables for increasing membrane flux without increasing the fouling.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1,6,8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP-3221095-B in view of JP 2000-107758 or JP 63-028406.

JP-3221095 teaches a hollow fiber membranes and device as in claims 1,8 and 10, and method of making the hollow fiber as in claim 6. JP-095 teaches fibrillated structure made of PTFE for support tube and rejection layer as claimed, which is obtained by uniaxial or biaxial stretching, laminating the rejection layer to the support tube, rejection layer of PTFE sheet having smaller pore size than the support layer. The support layer is outside and rejection layer is inside the tube for inside to outside filtration in JP-095. See the text of the reference and the figures. Affording unevenness to the outer surface of the expanded PTFE tube with respect to the process is inherent, since the surface would be uneven due to porosity and also due to the stretching (see paragraph 5).

Applicant's claims differ from the teaching of JP-095 in the recitation of the rejection layer on the outside and support inside for outside-in filtration. However, the JP-095 reference teaches that outside-in structures are known in the art (see paragraphs 0007, 0008), and the teaching of the reference is for specific applications wherein the flow is inside-out. The structure is also otherwise similar – a fibrillated support structure supporting another fibrillated rejection layer. The reference in the table also has an example of a membrane with outside rejection layer. The outside-in or inside-out filtration would also be obvious to one of ordinary skill in the art since such types of filtrations with hollow fibers are well known in the art, and one would choose to have the filtration layer facing the fluid to be filtered. References JP 63-028406 and JP 2000-107758 teach outside-in filtration, and both references teach fibrillated porous supports and laminated structures. In JP-406, the filtration layer is on the outside similar to the applicant's claims. In JP-758, there is an additional support for the filtration layer from the outside. One would use the teaching of JP-406 or JP-758 in the teaching of JP-095 depending on the type of fluids to be filtered such as blood or water having high amounts of suspended matter for outside-in filtration.

With respect to the limitations in claim 1 as to the relation between the maximum average fiber length (L), particle size (X), RFL and factor (Y), such a relation at best is an optimization process for membrane pore size to the type of fluid to be filtered (such as the suspended matter particle size) for most efficient filtration, such as maximizing the flux, without increasing membrane fouling. For example, consider applicant's comparative example 1. The value of (X) is 0.2 μm, (L) is 15 μm, (L/X) is 75, and the point does not fall within the region defined, as shown in the example. However, for the same membrane, if the (X) value were to be 2.0 μm, (L/X) would be 7.5, and it would fall in the region. If the membrane could trap 0.2 μm particles to above 90%, it would also definitely trap 2 μm particles to above 90%. Thus, this limitation would reduce to just ***optimizing the membrane usage*** for a particular particle size for low fouling and high flux. Discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art. In re Boesch and Slaney, 205 USPQ 215 (CCPA 1980); In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977); "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). This limitation also would be only directed to an intended use of the membrane; it is not structurally limiting. A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987)

Regarding the ratio of pore diameters between the filtration layer and the support layer, see paragraphs 23 and 24 of the reference. Filtration layer pore size is 0.01 – 10 μm; the support pore size can be optimized as indicated in paragraph 23.

Response to Arguments

Applicant's arguments filed 6/6/07 have been fully considered but they are not persuasive.

With respect to the declaration submitted by Mr. Morita, the declaration is not sufficient to overcome the rejection. First of all, the rejection is not based on inherency, even though the membrane of the reference would fall in the region defined in claim 1 for some value of (X). Secondly, the declaration does not provide sufficient details as to how the two membranes were manufactured. Paragraph [0024] of the JP-095 reference (see the English translation in file) describes that the PTFE sheet used with the present invention can be manufactured using different types according to pore diameter, porosity, pore structure, thickness, uniaxial or biaxial stretching, etc. Therefore, it is difficult to believe that one will not be able to make a composite membrane using the method of JP-095 that would fall in the region claimed. The cited paragraph teaches that the pore openings can be made “mesh-like” by biaxial stretching, in which case the (Y) value can be tailored pretty close to 1.

It appears to the Examiner that applicant has a correlation, or a test, in which the average of the maximum fibril lengths (L) measured using an SEM is divided by a particle size (X), (X is explained as the nominal pore size of the membrane in the response filed 6/6/07), and applicant is optimizing this ratio to fall within a region bounded by certain (X,Y) coordinates to obtain reduced fouling, or reduced flux loss with time. Ideally, one should have square-like (or mesh-like) pores in the stretched membrane rather than slit like pores, so that the particles would not be trapped in the pores and cause flux loss. A membrane that would pass this test would not be a patentable invention, because many membranes available in the market may pass this test. Moreover, applicant's definition of the test is also indefinite, as is shown in the rejection.

With respect to the membrane recited in the reference, the JP-095 reference teaches such a membrane – see table 1, which has the rejection layer on the outside in example 2, membrane B.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S. Menon whose telephone number is 571-272-1143. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David R. Sample can be reached on 571-272-1376. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KS Menon
6/20/07

Krishnan S Menon
Primary Examiner
Art Unit 1723